

## INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

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(81) Designated States: AE, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CR, CU, CZ, DE, DK, DM, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, US, UZ, VN, YU, ZA, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).

Published

With international search report.

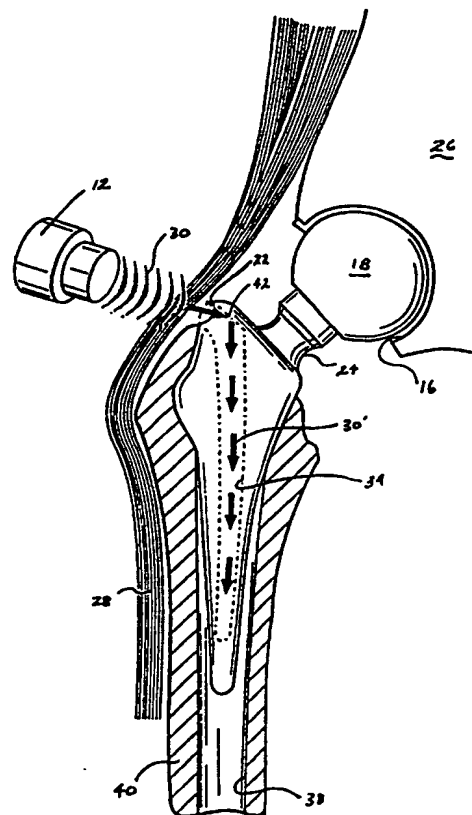
(88) Date of publication of the international search report:

23 November 2000 (23.11.00)

(54) Title: PROSTHESIS AND METHODS OF INDUCING BONY INGROWTH USING ULTRASOUND THERAPY

## (57) Abstract

A bone prosthesis (10) includes a first portion for engaging a first bone segment and at least one channel (34) disposed within the first portion for propagating acoustic energy through the channel to the first bone segment. The channel includes an interior reflective surface which defines a resonating chamber disposed through the first portion which propagates acoustic energy to the first bone segment to stimulate bony ingrowth. The present disclosure also relates to a method for measuring the stability of an implanted prosthesis which includes the steps of: a) providing a source (11) having a probe for sending and receiving signals and a comparator for comparing and analyzing prior signal data with newer signal data; b) placing the probe (15) adjacent the prosthesis; c) transmitting an initial signal through the probe to the prosthesis; d) receiving a return signal from the probe after the signal propagates and returns through the prosthesis; e) storing the return signal data; f) repeating steps (a) through (e); and g) comparing and analyzing stored return signal data to determine implant stabilization.



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EE	Estonia						

# INTERNATIONAL SEARCH REPORT

International Application No

PCT/US 99/26265

**A. CLASSIFICATION OF SUBJECT MATTER**  
IPC 7 A61F2/28 A61N7/00

According to International Patent Classification (IPC) or to both national classification and IPC

**B. FIELDS SEARCHED**

Minimum documentation searched (classification system followed by classification symbols)  
IPC 7 A61F A61N

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal

**C. DOCUMENTS CONSIDERED TO BE RELEVANT**

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 330 481 A (CAILLOUETTE JAMES T ET AL) 19 July 1994 (1994-07-19) column 9, line 42 - line 49	1
A	US 5 730 705 A (BOBYN J DENNIS ET AL) 24 March 1998 (1998-03-24) the whole document	1-31, 34
A	GB 2 277 448 A (THODIYIL PAUL ALBERT) 2 November 1994 (1994-11-02) abstract	1-31, 34
A	WO 98 34578 A (EXOGEN INC ; ROSE EMERY (US); RYABY JACK (US); TALISH ROGER J (US);) 13 August 1998 (1998-08-13) abstract; figure 12A	8
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☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

\* Special categories of cited documents :

- "A" document defining the general state of the art which is not considered to be of particular relevance
- "E" earlier document but published on or after the international filing date
- "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- "O" document referring to an oral disclosure, use, exhibition or other means
- "P" document published prior to the international filing date but later than the priority date claimed

- "T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
- "&" document member of the same patent family

Date of the actual completion of the international search

19 July 2000

Date of mailing of the international search report

0 2.08.00

Name and mailing address of the ISA

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Authorized officer

Korth, C-F

# INTERNATIONAL SEARCH REPORT

International Application No  
PCT/US 99/26265

## C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO 90 06720 A (ROSENSTEIN ALEXANDER D) 28 June 1990 (1990-06-28) the whole document	32,33
A	DE 36 39 263 A (HIGO YAKICHI) 25 June 1987 (1987-06-25) abstract	32,33
A	GB 2 156 983 A (CRAWFORD ALAN; ENGLAND DAVID; HICKS BRIAN; NOKES LEN; FAIRCLOUGH JOHN;) 16 October 1985 (1985-10-16) abstract	32,33

# INTERNATIONAL SEARCH REPORT

International application No.  
PCT/US 99/26265

## Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:  
because they relate to subject matter not required to be searched by this Authority, namely:
2. ☐ Claims Nos.:  
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
3. ☐ Claims Nos.:  
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

## Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

see additional sheet

1. ☒ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☒ No protest accompanied the payment of additional search fees.

**FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210**

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. Claims: 1-31,34

2. Claims: 32,33

# INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/US 99/26265

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
US 5330481	A	19-07-1994	US 5019083 A	28-05-1991
			US 5045054 A	03-09-1991
			US 5284484 A	08-02-1994
			US 5456686 A	10-10-1995
			US 5324297 A	28-06-1994
			US 5318570 A	07-06-1994
			US 5382251 A	17-01-1995
			AU 7308521 A	03-09-1991
			WO 9111965 A	22-08-1991
US 5730705	A	24-03-1998	NONE	
GB 2277448	A	02-11-1994	NONE	
WO 9834578	A	13-08-1998	AU 6434698 A	26-08-1998
			EP 0977534 A	09-02-2000
WO 9006720	A	28-06-1990	CA 2006133 A,C	21-06-1990
			EP 0449881 A	09-10-1991
			JP 2246923 A	02-10-1990
			US 5024239 A	18-06-1991
DE 3639263	A	25-06-1987	JP 1853740 C	07-07-1994
			JP 5069542 B	01-10-1993
			JP 62117553 A	29-05-1987
			DE 3645212 C	30-11-1995
			US 4819753 A	11-04-1989
GB 2156983	A	16-10-1985	NONE	

14/14

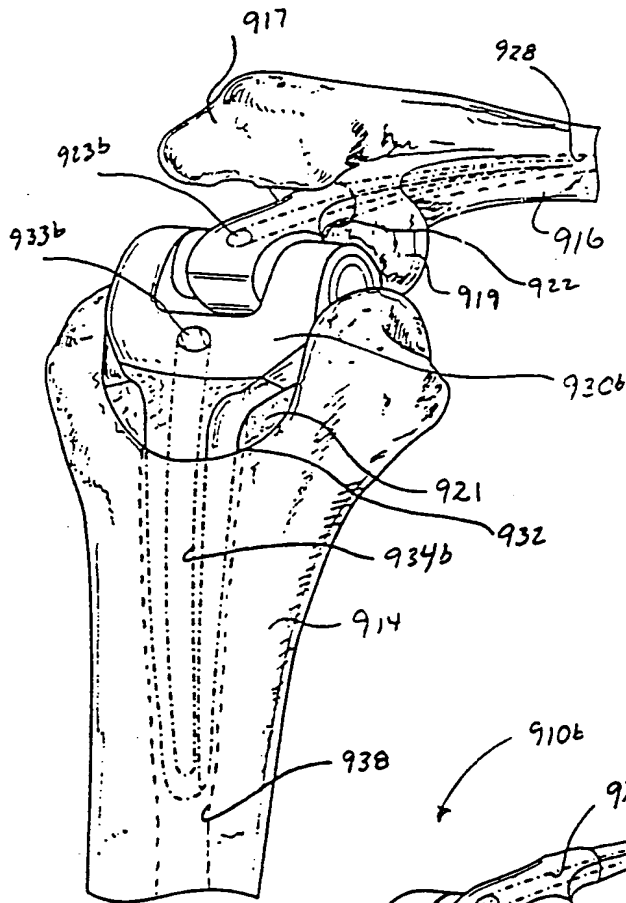


FIG. 13A

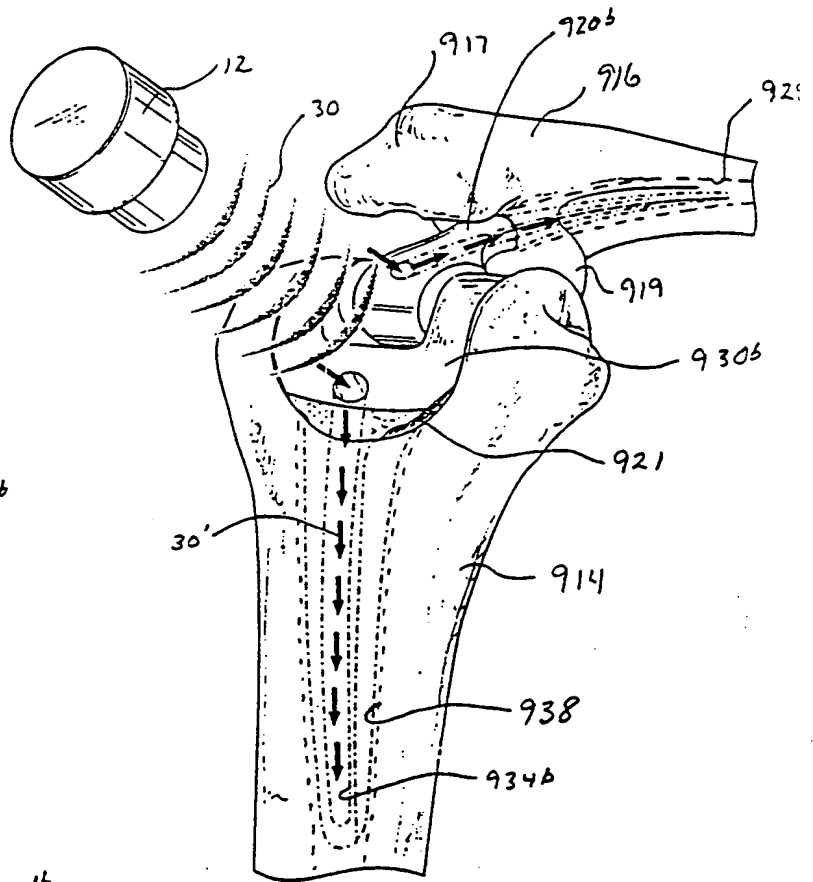


FIG. 13B

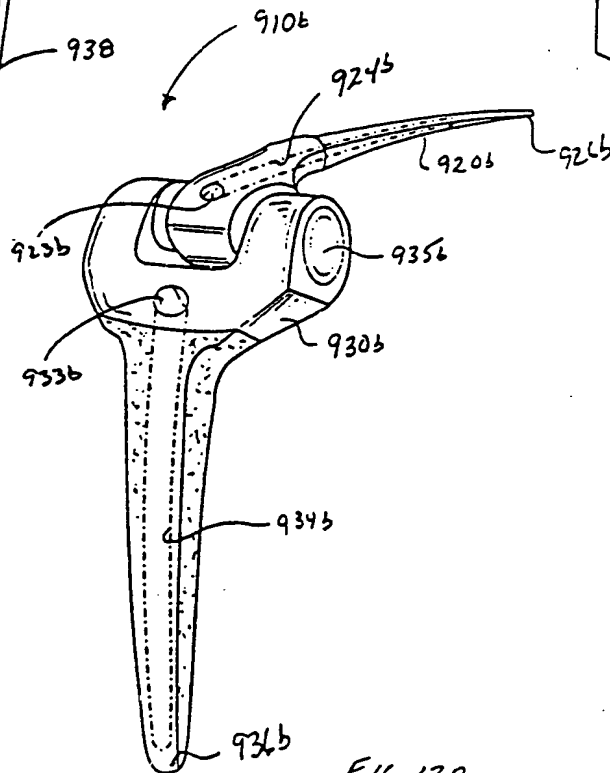


FIG. 13C





## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 601-54 PCT/01669-...	<b>FOR FURTHER ACTION</b> See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/US99/26265	International filing date (day/month/year) 12/11/1999	Priority date (day/month/year) 13/11/1998
International Patent Classification (IPC) or national classification and IPC A61F2/28		
Applicant EXOGEN, INC. et al.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.



2. This REPORT consists of a total of 6 sheets, including this cover sheet.

- ☒ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of 6 sheets.

3. This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☒ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV ☒ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☒ Certain defects in the international application
- VIII ☐ Certain observations on the international application

Date of submission of the demand  13/06/2000	Date of completion of this report  20.02.01
Name and mailing address of the international preliminary examining authority:   European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized officer  Hedels, B  Telephone No. +49 89 2399 2329 

# INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/US99/26265

## I. Basis of the report

1. This report has been drawn on the basis of *(substitute sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to the report since they do not contain amendments (Rules 70.16 and 70.17).)*:  
**Description, pages:**

1-31 as originally filed

### Claims, No.:

1-34 as received on 15/01/2001 with letter of 15/01/2001

### Drawings, sheets:

1/14-14/14 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
- ☐ the claims, Nos.:

# INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/US99/26265

☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)):  
(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

## III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application.

☒ claims Nos. 34.

because:

☒ the said international application, or the said claims Nos. 34 relate to the following subject matter which does not require an international preliminary examination (*specify*):  
**see separate sheet**

☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. are so unclear that no meaningful opinion could be formed (*specify*):

☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

☐ no international search report has been established for the said claims Nos. .

2. A meaningful international preliminary examination report cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

☐ the written form has not been furnished or does not comply with the standard.

☐ the computer readable form has not been furnished or does not comply with the standard.

## IV. Lack of unity of invention

1. In response to the invitation to restrict or pay additional fees the applicant has:

☐ restricted the claims.

# INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/US99/26265

- ☒ paid additional fees.
- ☐ paid additional fees under protest.
- ☐ neither restricted nor paid additional fees.
2. ☐ This Authority found that the requirement of unity of invention is not complied and chose, according to Rule 68.1, not to invite the applicant to restrict or pay additional fees.
3. This Authority considers that the requirement of unity of invention in accordance with Rules 13.1, 13.2 and 13.3 is
- ☐ complied with.
- ☒ not complied with for the following reasons:  
**see separate sheet**
4. Consequently, the following parts of the international application were the subject of international preliminary examination in establishing this report:
- ☐ all parts.
- ☒ the parts relating to claims Nos. 1-33.

## V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

### 1. Statement

Novelty (N)	Yes:	Claims	32,33
	No:	Claims	1,2,4,5,6,7,8,10
Inventive step (IS)	Yes:	Claims	32,33
	No:	Claims	3,9,11-31
Industrial applicability (IA)	Yes:	Claims	1-33
	No:	Claims	

### 2. Citations and explanations **see separate sheet**

## VII. Certain defects in the international application

The following defects in the form or contents of the international application have been noted:  
**see separate sheet**

**INTERNATIONAL PRELIMINARY  
EXAMINATION REPORT - SEPARATE SHEET**

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International application No. PCT/US99/26265

1. The application does not meet the requirement of unity according to Rule 13.1.

- The independent claim 1 relates to a bone prosthesis comprising means (a channel) for propagating acoustic energy through said means.
- The methods defined in the independent claims 32,33 serve for measuring the stability of an implanted prosthesis.

There are no common "special technical features" in terms of Rule 13.2 linking the above matters.

Following the invitation to restrict the application or to pay additional fees, the applicant paid an additional examination fee.

The international preliminary examination is therefore carried out for claims 1-33.

2. A bone prosthesis comprising a first portion for engaging a bone segment and means (channel) for propagating acoustic energy to said bone segment, as defined in claim 1, is disclosed in US-A-5 330 481 (D1) (see Fig. 2C and the corresponding description).

Hence, the subject-matter of claim 1 does not meet the requirement of novelty (Art. 33(2) PCT).

3. This objection also applies to the dependent claims 2 (see D1, Fig. 2A), claims 4,5,6 and 7 (see the tapped hole in Fig. 2C), and claims 8 and 10 (see the transducers (adapters) mentioned throughout the description of D1 e.g. column 9, lines 50-54).

Thus, the features defined in these claims also lack novelty.

4. As far as the features of claims 2,9 and 11-31 are not explicitly disclosed in D1, they are either obvious in view of the fact that the disclosure of D1 is not restricted to hip joint prostheses but also relates to knee joints (see D1, column 12, lines 22-28), or these features merely relate to minor constructional modifications which are not inventive (Art. 33(3) PCT).

5. The methods defined in the independent claims 32 and 33 differ in that according to claim 32 only a single probe (for sending and receiving) is necessary whereas according to claim 33 two probes (one for sending and one for receiving signals) are necessary (see Figs. 8 and 9).

Both methods have in common the method step of comparing and analysing stored return signal data. This feature appears to be novel and inventive since it cannot be derived in an obvious manner from the cited documents.

By means of such a comparison the implant stabilisation can be determined.

Such methods are also industrially applicable such that all the requirements of Art. 33(2)-(4) are met.

6. The independent claim 34 containing the method steps of "engaging said first portion within a first bone segment ... and directing acoustic energy at said first portion to stimulate bony ingrowth" clearly relate to a method for treatment of the human or animal body by surgery or therapy.

The International Preliminary Examining Authority is not required to carry out an international preliminary examination on such claims (Rule 67.1(iv)).

Claim 34 should therefore have been deleted.

7. Claim 1 should have been delimited with respect to D1 as the closest prior art (Rule 6.3 (b)).

8. In order to be able to assess the question of inventive step, the applicant should have indicated which technical problem is solved by the characterising features of claim 1 compared to device of D1 (Rule 5.1 (a) (iii)).

9. The description should have to be brought into line with the new claims (Rule 5.1 (a) (iii)).

10. D1 should have been indicated in the description (Rule 5.1 (a) (ii)).

**WHAT IS CLAIMED IS:**

1. A bone prosthesis, comprising:  
a first portion for engaging a first bone segment;  
said first portion including at least one channel for propagating acoustic energy through said channel to said first bone segment.
2. A bone prosthesis according to claim 1 further comprising a second portion for engaging a second bone segment.
3. A bone prosthesis according to claim 1 wherein said channel includes an interior reflective surface which defines a resonating chamber disposed through said first portion.
4. A bone prosthesis according to claim 2 wherein said channel includes an interior reflective surface which defines a resonating chamber disposed through at least one of said portions.
5. A bone prosthesis according to claim 3 wherein said resonating chamber includes at least one opening for receiving acoustic energy.

6. A bone prosthesis according to claim 5, wherein said resonating chamber is convoluted.
7. A bone prosthesis according to claim 1 wherein said prosthesis further comprises a transducer disposed adjacent said portion which receives acoustic energy and emits acoustic waves through said channel.
8. A bone prosthesis, comprising:
  - a first portion for engaging a first bone segment;
  - a second portion for engaging a second bone segment; and
  - at least one of said portions including at least one means for propagating acoustic energy to said corresponding bone segment.
9. A bone prosthesis according to claim 8 wherein said means for propagating comprises a transducer collar which engages one of said portions.
10. A bone prosthesis according to claim 8 wherein said means for propagating includes a transducer disposed adjacent at least one of said portions.



11. A bone prosthesis according to claim 8 wherein at least one of said portions includes a porous coating wrapped therearound.
12. A bone prosthesis according to claim 11 wherein said means for propagating includes a piezoelectric membrane material which is disposed between said porous material and an outer periphery of said portion.
13. A bone prosthesis according to claim 11 wherein said means for propagating includes a piezoceramic membrane material which is disposed between said porous material and an outer periphery of said portion.
14. A bone prosthesis according to claim 1 wherein the prosthesis includes a ball portion for engaging the acetabulum of the pelvic bone and said first portion is an implant for engaging the medullary canal of the femur.
15. A bone prosthesis according to claim 14 wherein said channel includes an interior reflective surface which defines a resonating chamber disposed through said implant.
16. A bone prosthesis according to claim 15 wherein said resonating chamber includes at least one opening for receiving acoustic energy.

17. A bone prosthesis according to claim 14 wherein an outer periphery of said implant is patterned to promote acoustic wave propagation along an outer surface of said implant.
18. A bone prosthesis according to claim 15 wherein said resonating chamber includes a plurality of slots which extend outwardly from said resonating chamber to transmit acoustic energy directly to the medullary canal.
19. A bone prosthesis according to claim 1 wherein the first portion engages the medullary canal of the humerus and a second portion engages the medullary canal of the ulna; and wherein said first and second portions are movable relative to one another about a pivot.
20. A bone prosthesis according to claim 19 wherein each of said portions includes a channel, each of said channels including an interior reflective surface which defines a resonating chamber disposed through each of said portions.
21. A bone prosthesis according to claim 20 wherein each of said resonating chambers includes at least one opening for receiving acoustic energy.

22. A bone prosthesis according to claim 19 wherein an outer periphery of at least one of said portions is patterned to promote acoustic wave propagation along an outer surface of said portion.
23. A bone prosthesis according to claim 1 wherein the first portion engages the femur and a second portion engages the tibia, said first and second portions being movable relative to one another upon movement of one of the femur and the tibia.
24. A bone prosthesis according to claim 23 wherein said first portion includes at least one dowel which engages a corresponding bore associated with the femur and said second portion includes at least one dowel which engages a corresponding bore associated with the tibia.
25. A bone prosthesis according to claim 24 wherein said channel includes an interior reflective surface which defines a resonating chamber disposed through each of said dowels.
26. A bone prosthesis according to claim 25 wherein each of said resonating chambers includes at least one aperture for receiving acoustic energy.

27. A bone prosthesis according to claim 23 wherein said first and second portions include outer surfaces which pivotally engage one another and bone-facing inner surfaces which engage the femur and tibia, respectively.
28. A bone prosthesis according to claim 27 wherein said first portion is generally U-shaped and encompasses the patella of the femur and said second portion is generally T-shaped and fits atop the tibia.
29. A bone prosthesis according to claim 27 wherein said channel includes a plurality of grooves located along said bone-facing inner surface of one of said first and second portions.
30. A bone prosthesis according to claim 24 wherein at least one of said dowels of said first and second portions includes a plurality of grooves for propagating acoustic energy therethrough.
31. A bone prosthesis according to claim 27 wherein said outer surface of said second portion includes at least one recess for seating the outer surface of said first portion in a cradle-like manner.

32. A method for measuring the stability of an implanted prosthesis comprising the steps of:

- a) providing a source having a probe for sending and receiving signals and a comparator for comparing and analyzing prior signal data with newer signal data;
- b) placing said probe adjacent said prosthesis;
- c) transmitting an initial signal through said probe to said prosthesis;
- d) receiving a return signal from said probe after said signal propagates and returns through said prosthesis;
- e) storing said return signal data;
- f) repeating steps (a) through (e); and
- g) comparing and analyzing stored return signal data to determine implant stabilization.

33. A method for measuring the stability of an implanted prosthesis comprising the steps of:

- a) providing a source having a probe for sending signals and a comparator for comparing and analyzing prior signal data with newer signal data;
- b) providing a receiving sensor which connects to said source and monitors said signals as said signals propagate through said prosthesis;
- c) placing said probe adjacent said prosthesis;
- d) placing said receiving sensor along said prosthesis;

- e) transmitting signals through said probe to said prosthesis;
- f) monitoring said signal with said receiving sensor as said signal propagates through said prosthesis;
- g) storing said signal data;
- h) repeating steps (a) through (g); and
- i) comparing and analyzing stored signal data to determine implant stabilization.

34. A method for stabilizing an implanted prosthesis comprising the steps of:

- a) providing a bone prosthesis having a first portion and at least one channel for propagating acoustic energy therethrough;
- b) engaging said first portion within a first bone segment; and
- c) periodically directing acoustic energy at said first portion such that acoustic energy is transmitted through said channel to said first bone segment to stimulate bony ingrowth.

# PATENT COOPERATION TREATY

From the  
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To:

Zinnecker  
LORENZ, SEIDLER, GOSSEL  
Widenmayerstraße 23  
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21. FEB. 2001

Frist

## PCT

NOTIFICATION OF TRANSMITTAL OF  
THE INTERNATIONAL PRELIMINARY  
EXAMINATION REPORT  
(PCT Rule 71.1)

Date of mailing  
(day/month/year)

20.02.01

Applicant's or agent's file reference  
601-54 PCT/01669-...

### IMPORTANT NOTIFICATION

International application No.  
PCT/US99/26265

International filing date (day/month/year)  
12/11/1999

Priority date (day/month/year)  
13/11/1998

Applicant  
EXOGEN, INC. et al.

1. The applicant is hereby notified that this International Preliminary Examining Authority transmits herewith the international preliminary examination report and its annexes, if any, established on the international application.
2. A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all the elected Offices.
3. Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report (but not of any annexes) and will transmit such translation to those Offices.

#### 4. REMINDER

The applicant must enter the national phase before each elected Office by performing certain acts (filing translations and paying national fees) within 30 months from the priority date (or later in some Offices) (Article 39(1)) (see also the reminder sent by the International Bureau with Form PCT/IB/301).

Where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary examination report. It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned.

For further details on the applicable time limits and requirements of the elected Offices, see Volume II of the PCT Applicant's Guide.

Name and mailing address of the IPEA/



European Patent Office  
D-80298 Munich  
Tel. +49 89 2399 - 0 Tx: 523556 epmu d  
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Authorized officer

Terzic, K

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# PCT

## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 601-54 PCT/01669-...	<b>FOR FURTHER ACTION</b> See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/US99/26265	International filing date (day/month/year) 12/11/1999	Priority date (day/month/year) 13/11/1998
International Patent Classification (IPC) or national classification and IPC A61F2/28		
Applicant EXOGEN, INC. et al.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.



2. This REPORT consists of a total of 6 sheets, including this cover sheet.

☒ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of 6 sheets.

3. This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☒ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV ☒ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☒ Certain defects in the international application
- VIII ☐ Certain observations on the international application

Date of submission of the demand 13/06/2000	Date of completion of this report 20.02.01
Name and mailing address of the international preliminary examining authority:  European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized officer Hedels, B Telephone No. +49 89 2399 2329 



**INTERNATIONAL PRELIMINARY  
EXAMINATION REPORT**

International application No. PCT/US99/26265

**I. Basis of the report**

1. This report has been drawn on the basis of *(substitute sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to the report since they do not contain amendments (Rules 70.16 and 70.17).):*

**Description, pages:**

1-31 as originally filed

**Claims, No.:**

1-34 as received on 15/01/2001 with letter of 15/01/2001

**Drawings, sheets:**

1/14-14/14 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
- ☐ the claims, Nos.:

# INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/US99/26265

☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)):

*(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)*

6. Additional observations, if necessary:

## III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application.

☒ claims Nos. 34.

because:

☒ the said international application, or the said claims Nos. 34 relate to the following subject matter which does not require an international preliminary examination (*specify*):  
**see separate sheet**

☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. are so unclear that no meaningful opinion could be formed (*specify*):

☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

☐ no international search report has been established for the said claims Nos. .

2. A meaningful international preliminary examination report cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

☐ the written form has not been furnished or does not comply with the standard.

☐ the computer readable form has not been furnished or does not comply with the standard.

## IV. Lack of unity of invention

1. In response to the invitation to restrict or pay additional fees the applicant has:

☐ restricted the claims.

**INTERNATIONAL PRELIMINARY  
EXAMINATION REPORT**

International application No. PCT/US99/26265

- ☒ paid additional fees.
- ☐ paid additional fees under protest.
- ☐ neither restricted nor paid additional fees.
2. ☐ This Authority found that the requirement of unity of invention is not complied and chose, according to Rule 68.1, not to invite the applicant to restrict or pay additional fees.
3. This Authority considers that the requirement of unity of invention in accordance with Rules 13.1, 13.2 and 13.3 is
- ☐ complied with.
- ☒ not complied with for the following reasons:  
**see separate sheet**
4. Consequently, the following parts of the international application were the subject of international preliminary examination in establishing this report:
- ☐ all parts.
- ☒ the parts relating to claims Nos. 1-33.

**V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

1. Statement

Novelty (N)	Yes:	Claims	32,33
	No:	Claims	1,2,4,5,6,7,8,10
Inventive step (IS)	Yes:	Claims	32,33
	No:	Claims	3,9,11-31
Industrial applicability (IA)	Yes:	Claims	1-33
	No:	Claims	

2. Citations and explanations  
**see separate sheet**

**VII. Certain defects in the international application**

The following defects in the form or contents of the international application have been noted:  
**see separate sheet**

**INTERNATIONAL PRELIMINARY  
EXAMINATION REPORT - SEPARATE SHEET**

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International application No. PCT/US99/26265

1. The application does not meet the requirement of unity according to Rule 13.1.

- The independent claim 1 relates to a bone prosthesis comprising means (a channel) for propagating acoustic energy through said means.
- The methods defined in the independent claims 32,33 serve for measuring the stability of an implanted prosthesis.

There are no common "special technical features" in terms of Rule 13.2 linking the above matters.

Following the invitation to restrict the application or to pay additional fees, the applicant paid an additional examination fee.

The international preliminary examination is therefore carried out for claims 1-33.

2. A bone prosthesis comprising a first portion for engaging a bone segment and means (channel) for propagating acoustic energy to said bone segment, as defined in claim 1, is disclosed in US-A-5 330 481 (D1) (see Fig. 2C and the corresponding description).

Hence, the subject-matter of claim 1 does not meet the requirement of novelty (Art. 33(2) PCT).

3. This objection also applies to the dependent claims 2 (see D1, Fig. 2A), claims 4,5,6 and 7 (see the tapped hole in Fig. 2C), and claims 8 and 10 (see the transducers (adapters) mentioned throughout the description of D1 e.g. column 9, lines 50-54).

Thus, the features defined in these claims also lack novelty.

4. As far as the features of claims 2,9 and 11-31 are not explicitly disclosed in D1, they are either obvious in view of the fact that the disclosure of D1 is not restricted to hip joint prostheses but also relates to knee joints (see D1, column 12, lines 22-28), or these features merely relate to minor constructional modifications which are not inventive (Art. 33(3) PCT).

**INTERNATIONAL PRELIMINARY  
EXAMINATION REPORT - SEPARATE SHEET**

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International application No. PCT/US99/26265

5. The methods defined in the independent claims 32 and 33 differ in that according to claim 32 only a single probe (for sending and receiving) is necessary whereas according to claim 33 two probes (one for sending and one for receiving signals) are necessary (see Figs. 8 and 9).

Both methods have in common the method step of comparing and analysing stored return signal data. This feature appears to be novel and inventive since it cannot be derived in an obvious manner from the cited documents.

By means of such a comparison the implant stabilisation can be determined.

Such methods are also industrially applicable such that all the requirements of Art. 33(2)-(4) are met.

6. The independent claim 34 containing the method steps of "engaging said first portion within a first bone segment ... and directing acoustic energy at said first portion to stimulate bony ingrowth" clearly relate to a method for treatment of the human or animal body by surgery or therapy.

The International Preliminary Examining Authority is not required to carry out an international preliminary examination on such claims (Rule 67.1(iv)).

Claim 34 should therefore have been deleted.

7. Claim 1 should have been delimited with respect to D1 as the closest prior art (Rule 6.3 (b)).

8. In order to be able to assess the question of inventive step, the applicant should have indicated which technical problem is solved by the characterising features of claim 1 compared to device of D1 (Rule 5.1 (a) (iii)).

9. The description should have to be brought into line with the new claims (Rule 5.1 (a) iii)).

10. D1 should have been indicated in the description (Rule 5.1 (a) (ii)).

CLAIMS

1. A bone prosthesis (10) comprising a first portion (32) for  
engaging a first bone segment (14) characterised in that the  
bone prosthesis (10) further comprises at least one means for  
propagating acoustic energy (30) to said first bone segment  
(14).
2. A bone prosthesis (10) according to claim 1 further comprising  
a second portion for engaging a second bone segment (26).
3. A bone prosthesis (10) according to claim 2 in which comprises  
at least one means for propagating acoustic energy to said  
second bone segment.
4. A bone prosthesis (10) as claimed in either of claims 1, 2 or 3  
in which the at least one means for propagating acoustic  
energy to the corresponding bone segment comprises at least  
one channel.
5. A bone prosthesis (10) according to claim 4 wherein said  
channel includes an interior reflective surface (42) which defines  
a resonating chamber (34) disposed through at least one of  
said portions (14, 18).
6. A bone prosthesis (10) according to claim 5 wherein said  
resonating chamber (34) includes at least one opening (22) for  
receiving acoustic energy.
7. A bone prosthesis (10) according to claim 6, wherein said  
resonating chamber (34) is convoluted.
8. A bone prosthesis (10) according to any one of claims 4 to 7  
wherein said bone prosthesis (10) further comprises a  
transducer (144) disposed to receive acoustic energy (30) and  
emit acoustic waves (30') through said channel.
9. A bone prosthesis (10) according to claim 2 wherein said  
means for propagating comprises a transducer collar (546)  
which engages one of said portions.

10. A bone prosthesis (10) according to claim 2 wherein said means for propagating includes a transducer (144) disposed adjacent at least one of said portions.
- 5 11. A bone prosthesis (10) according to claim 2 wherein at least one of said portions includes a porous coating wrapped therearound.
- 10 12. A bone prosthesis (10) according to claim 11 wherein said means for propagating includes a piezoelectric membrane material which is disposed between said porous material and an outer periphery of said portion.
13. A bone prosthesis (10) according to claim 11 wherein said means for propagating includes a piezoceramic membrane material which is disposed between said porous material and an outer periphery of said portion.
- 15 14. A bone prosthesis (10) according to claim 4 wherein the prosthesis includes a ball portion for engaging the acetabulum (16) of the pelvic bone (26) and said first portion is an implant for engaging the medullary canal (38) of the femur (14).
- 20 15. A bone prosthesis (10) according to claim 14 wherein said channel includes an interior reflective surface (42) which defines a resonating chamber (34) disposed through said implant.
- 25 16. A bone prosthesis (10) according to claim 15 wherein said resonating chamber (34) includes at least one opening (22) for receiving acoustic energy (30).
17. A bone prosthesis (10) according to claim 14 wherein an outer periphery of said implant (732) is patterned to promote acoustic wave propagation along an outer surface of said implant.
- 30 18. A bone prosthesis (10) according to claim 15 wherein said resonating chamber (34) includes a plurality of slots which

extend outwardly from said resonating chamber (34) to transmit acoustic energy (30) directly to the medullary canal (38).

- 5 19. A bone prosthesis (10) according to claim 4 wherein the first portion engages the medullary canal (38) of the humerus and a second portion engages the medullary canal of the ulna; and wherein said first and second portions are movable relative to one another about a pivot.
- 10 20. A bone prosthesis (10) according to claim 19 wherein each of said portions includes a channel, each of said channels including an interior reflective surface (42) which defines a resonating chamber (34) disposed through each of said portions.
- 15 21. A bone prosthesis (10) according to claim 20 wherein each of said resonating chambers (34) includes at least one opening (22) for receiving acoustic energy (30).
22. A bone prosthesis (10) according to claim 19 wherein an outer periphery (732) of at least one of said portions is patterned to promote acoustic wave propagation along an outer surface of said portion.
- 20 23. A bone prosthesis (10) according to claim 4 wherein the first portion engages the femur (14) and a second portion engages the tibia, said first and second portions being movable relative to one another upon movement of one of the femur and the tibia (818).
- 25 24. A bone prosthesis (10) according to claim 23 wherein said first portion includes at least one dowel (842a, 832a) which engages a corresponding bore associated with the femur (14) and said second portion includes at least one dowel (842a, 832a) which engages a corresponding bore with the tibia (818).
- 30 25. A bone prosthesis (10) according to claim 24 wherein said channel includes an interior reflective surface (42) which



defines a resonating chamber (34) disposed through each of said dowels (842a, 832a).

- 5 26. A bone prosthesis (10) according to claim 25 wherein each of said resonating chambers (34) includes at least one aperture (22) for receiving acoustic energy (30).
27. A bone prosthesis (10) according to claim 23 wherein said first and second portions include outer surfaces which pivotally engage one another and bone-facing inner surfaces which engages the femur (14) and tibia (818) respectively.
- 10 28. A bone prosthesis (10) according to claim 27 wherein said first portion is generally U-shaped and encompasses the patella of the femur (14) and said second portion is generally T-shaped and fits atop the tibia (818).
- 15 29. A bone prosthesis (10) according to claim 27 wherein said channel includes a plurality of grooves located along said bone-facing inner surface of one of said first and second portions.
- 20 30. A bone prosthesis (10) according to claim 24 wherein at least one of said dowels of said first and second portions includes a plurality of grooves for propagating acoustic energy (30) therethrough.
- 25 31. A bone prosthesis (10) according to claim 27 wherein said outer surface of said second portion includes at least one recess for seating the outer surface of said first portion in a cradle-like manner.
- 30 32. A method for measuring the stability of an implanted prosthesis (10) comprising the steps of:
- a) providing a source having a probe for sending and receiving signals and a comparator for comparing and analysing prior signal data with newer signal data;

- b) placing said probe adjacent said prosthesis (10);
  - c) transmitting an initial signal through said probe to said prosthesis (10);
  - d) receiving a return signal from said probe after said signal propagates and returns through said prosthesis (10);
  - e) storing said return signal data;
  - f) repeating steps (a) through (e); and
  - g) comparing and analysing stored return signal data to determine implant stabilization.
33. A method for measuring the stability of an implanted prosthesis (10) comprising the steps of;
- a) providing a source having a probe for sending signals and a comparator for comparing and analysing prior signal data with newer signal data;
  - b) providing a receiving sensor which connects to said source and monitors said signals as said signals propagate through said prosthesis (10);
  - c) placing said probe adjacent said prosthesis (10);
  - d) placing said receiving sensor along said prosthesis (10);
  - e) transmitting signals through said probe to said prosthesis (10);
  - f) monitoring said signal with said receiving sensor as said signal propagates through said prosthesis (10);
  - g) storing said signal data;
  - h) repeating steps (a) through (g); and

- i) comparing and analysing stored signal data to determine implant stabilization.

34. A method for stabilizing an implanted prosthesis (10) comprising the steps of:

- 5      a) providing a bone prosthesis (10) having a first portion and at least one channel for propagating acoustic energy (30) therethrough;
- b) engaging said first portion within a first a bone segment; and
- 10     c) periodically directing acoustic energy (30) at said first portion such that acoustic energy (30) is transmitted through said channel to said first bone segment to stimulate bony ingrowth.

## PATENT COOPERATION TREATY

PCT

## NOTIFICATION OF ELECTION

(PCT Rule 61.2)

From the INTERNATIONAL BUREAU

To:

Assistant Commissioner for Patents  
United States Patent and Trademark  
Office  
Box PCT  
Washington, D.C.20231  
ETATS-UNIS D'AMERIQUE

in its capacity as elected Office

<b>Date of mailing (day/month/year)</b> 11 July 2000 (11.07.00)	
<b>International application No.</b> PCT/US99/26265	<b>Applicant's or agent's file reference</b> 601-54 PCT
<b>International filing date (day/month/year)</b> 12 November 1999 (12.11.99)	<b>Priority date (day/month/year)</b> 13 November 1998 (13.11.98)
<b>Applicant</b> TALISH, Roger, J. et al	

1. The designated Office is hereby notified of its election made:

☒ in the demand filed with the International Preliminary Examining Authority on:  
13 June 2000 (13.06.00)

☐ in a notice effecting later election filed with the International Bureau on:

2. The election ☒ was  
☐ was not

made before the expiration of 19 months from the priority date or, where Rule 32 applies, within the time limit under Rule 32.2(b).

<b>The International Bureau of WIPO</b> 34, chemin des Colombettes 1211 Geneva 20, Switzerland	<b>Authorized officer</b> Juan Cruz
Facsimile No.: (41-22) 740.14.35	Telephone No.: (41-22) 338.83.38

## INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference <b>601-54 PCT</b>	<b>FOR FURTHER ACTION</b> see Notification of Transmittal of International Search Report (Form PCT/ISA/220) as well as, where applicable, item 5 below.	
International application No. <b>PCT/US 99/ 26265</b>	International filing date (day/month/year) <b>12/11/1999</b>	(Earliest) Priority Date (day/month/year) <b>13/11/1998</b>
Applicant <b>EXOGEN, INC. et al.</b>		

This International Search Report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This International Search Report consists of a total of 6 sheets.

☒ It is also accompanied by a copy of each prior art document cited in this report.

## 1. Basis of the report

- a. With regard to the **language**, the international search was carried out on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ the international search was carried out on the basis of a translation of the international application furnished to this Authority (Rule 23.1(b)).

- b. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international search was carried out on the basis of the sequence listing :

☐ contained in the international application in written form.

☐ filed together with the international application in computer readable form.

☐ furnished subsequently to this Authority in written form.

☐ furnished subsequently to this Authority in computer readable form.

☐ the statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

☐ the statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished

2. ☐ **Certain claims were found unsearchable** (See Box I).

3. ☒ **Unity of invention is lacking** (see Box II).

4. With regard to the **title**,

☒ the text is approved as submitted by the applicant.

☐ the text has been established by this Authority to read as follows:

5. With regard to the **abstract**,

☐ the text is approved as submitted by the applicant.

☒ the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box III. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. The figure of the **drawings** to be published with the abstract is Figure No. 1c

☒ as suggested by the applicant.

☐ because the applicant failed to suggest a figure.

☐ because this figure better characterizes the invention.

☐ None of the figures.

## Box III TEXT OF THE ABSTRACT (Continuation of item 5 of the first sheet)

Line 1 : Add "(10)" after "prostheis";  
Line 2 : Add "(34)" after "channel";  
Line 8 : Add "(11)" after "source";  
Line 10 : add "(15)" after "probe";

## INTERNATIONAL SEARCH REPORT

International Application No

PCT 99/26265

A. CLASSIFICATION OF SUBJECT MATTER  
 IPC 7 A61F2/28 A61N7/00

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61F A61N

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 330 481 A (CAILLOUETTE JAMES T ET AL) 19 July 1994 (1994-07-19) column 9, line 42 - line 49 ---	1
A	US 5 730 705 A (BOBYN J DENNIS ET AL) 24 March 1998 (1998-03-24) the whole document ---	1-31,34
A	GB 2 277 448 A (THODIYIL PAUL ALBERT) 2 November 1994 (1994-11-02) abstract ---	1-31,34
A	WO 98 34578 A (EXOGEN INC ; ROSE EMERY (US); RYABY JACK (US); TALISH ROGER J (US);) 13 August 1998 (1998-08-13) abstract; figure 12A ---	8
	-/--	

☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

\* Special categories of cited documents :

- "A" document defining the general state of the art which is not considered to be of particular relevance
- "E" earlier document but published on or after the international filing date
- "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- "O" document referring to an oral disclosure, use, exhibition or other means
- "P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search

19 July 2000

Date of mailing of the international search report

0 2.08.00

Name and mailing address of the ISA

European Patent Office, P.B. 5818 Patentlaan 2  
 NL - 2280 HV Rijswijk  
 Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,  
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Authorized officer

Korth, C-F

# INTERNATIONAL SEARCH REPORT

International Application No

PCT 99/26265

## C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO 90 06720 A (ROSENSTEIN ALEXANDER D) 28 June 1990 (1990-06-28) the whole document	32, 33
A	DE 36 39 263 A (HIGO YAKICHI) 25 June 1987 (1987-06-25) abstract	32, 33
A	GB 2 156 983 A (CRAWFORD ALAN; ENGLAND DAVID; HICKS BRIAN; NOKES LEN; FAIRCLOUGH JOHN;) 16 October 1985 (1985-10-16) abstract	32, 33



**FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210**

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. Claims: 1-31,34

2. Claims: 32,33

# INTERNATIONAL SEARCH REPORT

International application No.  
PCT/US 99/26265

## Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:  
because they relate to subject matter not required to be searched by this Authority, namely:
2. ☐ Claims Nos.:  
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
3. ☐ Claims Nos.:  
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

## Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

see additional sheet

1. ☒ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

### Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☒ No protest accompanied the payment of additional search fees.

# INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/99/26265

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
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